SECTION V

BASIS FOR PETITION

This petition seeks reclassification of Constrained Metal/Polymer Hip Prostheses from class III to class II. Long term data now exists that addresses the risks that originally led to placement of these devices into class III.

Although the published experience with constrained hips is relatively small in comparison to that of total hip arthroplasty is general; it is to be expected given the rather limited patient population and indications for which this device is intended. The published results that do exist have been critically analyzed through a peer review process. The results show consistency in pain relief, restoration of function, and reduction in recurrence of dislocation. This body of published literature provides reasonable assurance of safety and effectiveness of this device.

Additionally, there is considerable experience with constrained hip acetabular liners as part of a total hip system. The geometry, articulating interface, and fixation surfaces of the constrained hip prosthesis are typically very si: lar to those of marketed total hip prostheses components.

The following sections in this petition address the known risks and how they can be controlled, pre-clinical testing, labeling, and technique concerns that support the premise that these devices may be regulated by the FDA as class II devices. The known risks can be divided into risks associated with surgery in general, and risks that are specific to the implant. This petition addresses the risks that are specific to the device. Specific risks for this constrained hip are adequately controlled and minimized by the same published standards, guidance documents, GMP & quality systems requirements, and labeling requirements used to control class II metal/polymer hip replacement devices.

Since these acetabular liners are not interchangeable from manufacturer to manufacturer, it is important to the public health that a constrained hip acetabular liner can be supplied by each manufacturers of total hip prostheses. If a compatible constrained liner is not available to the surgeon, an entire well-fixed total hip prosthesis may have to be removed from a patient in order to allow implantation of a constrained liner. The option to supply a constrained liner must be afforded each manufacturer of total hip prostheses. Moreover, the risks associated with these devices can be adequately controlled in class II, which would allow manufacturers to market the device through the premarket notification process.

The experience with this device in the commercial marketplace prior to December 1996 demonstrates its safe and effective use when regulated with class II controls.